

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SHAW-NAE DIXON, THOMAS CASATELLI,
JEANETTE RIVERA, NATALIA YAKUBOVA,
CHRIS KING, ALISON MARCHESE, on behalf
of AM, JM, and MMV (her minor children),
WILLIAM MORRIS, GEORGE KABBEZ,
SHAW-NAE'S HOUSE, LLC, SALTY DOG
RESTAURANT, LTD, PER TAVERN CORP.
d/b/a THE KETTLE BLACK, CARGOSTORK
PARTIES, INC. d/b/a DO ME A FAVOR, and
INDEPENDENT RESTAURANT OWNERS
ASSOCIATION RESCUE, INC.,

Civil Action No. 21-CV-5090 (BMC)

Plaintiffs,

v.

ERIC ADAMS, in his official capacity as Mayor
of the City of New York and as successor to Bill
de Blasio, and THE CITY OF NEW YORK,

Defendants.

**REPLY BRIEF TO THE DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION
SEEKING LEAVE TO FILE AMENDED COMPLAINT**

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STATEMENT OF CASE

The proposed Amended Complaint lays out a compelling fact case that individuals and entities have been harmed by Mayor Eric Adams' ("Mayor") unconstitutional vaccine mandates, which are public policies in the form of Emergency Executive Orders ("EEO"s) promulgated by he and his predecessor, Mayor Bill de Blasio, as chief executive officers of The City of New York ("City"). The plaintiffs thus present actionable claims for injunctions, declaratory relief, and economic damages pursuant to 42 U.S.C. § 1983. Such EEOs include a still-existing employer vaccine mandate, promulgated December 13, 2021 ("Employer Mandate"), which remains in effect, and which is challenged by the plaintiffs. In fact, the Mayor has created a special exemption from the Employer Mandate for sports teams because New York teams were being placed at a competitive disadvantage by the mandate--as if City businesses were unaffected in the competitive national sphere.¹ Defendants' own expert witness herein, Dr. Jay Varma, has noted that the Employer Mandate now strikes out, and is subject to legal challenge as being arbitrary and capricious.

Moreover, the proposed Amended Complaint lays out in detail both the Mayor's lack of authority for promulgating the mandates, including the originally challenged EEOs 225, 226 and 228 ("Vaccine Passport"), and their illegality; issues which defendants, through their machinations, have caused not to be decided on the merits to this point as plainly is their wish. Now defendants seek shelter behind inapposite case law and this Court's vacated Order as to the Mayoral authority for the mandates, and suggests that the plaintiffs are dilatory since this motion is before the Court "almost one year since the Complaint was filed," when virtually all delay was

¹ <https://www1.nyc.gov/assets/home/downloads/pdf/executive-orders/2022/eeo-62.pdf>

occasioned by defendants themselves. Such arguments by defendants are specious, and are not worthy of serious consideration.

The plaintiffs seek to amend their Complaint by expanding it to cover all EEOs which were promulgated by Mayors Adams and de Blasio, since all EEOs were promulgated without legal authority, and by bringing such challenge on behalf of all similarly situated individuals and businesses. Although this Court determined when originally deciding the preliminary injunction application that the Vaccine Passport was “issued pursuant to lawful processes under New York State law,” (Db 11), such determination preceded a more full development of facts, and also was vacated by the Second Circuit. There was no State emergency declaration in place when any of the EEOs were promulgated, such that the mayors lacked authority under the City’s Administrative Code (“Code”) to issue EEOs since the Code circumscribed “purported health emergencies” as being a basis for issuing EEOs pursuant to the emergency powers granted to the Mayor. Such issue was not visited by this Court.

Further, defendants incorrectly assert that “[t]he only new claim plaintiffs include in their proposed Amended Complaint,” is the presumption arising from the Emergency Use Authority (“EUA”) statute, 21 U.S.C. § 360bbb(e)(1)(A)(ii) (the “Statute”). In seeking to defeat preemption, defendants rely only on district court cases which do not analyze the issue. None of such cases is binding on this Court in any regard.

Finally, defendants’ baselessly assert that the Amended Complaint is moot. However, defendants fail to identify binding case law pursuant to § 1983, which contradicts their argument. Further, on this motion, defendants must be viewed as having purposely lifted the Vaccine Passport to avoid review. Thus, the issues have been evaded and have been made incapable of review by defendants. As our Supreme Court has held, “defendant’s voluntary cessation of allegedly unlawful

conduct ordinarily does not suffice to moot a case.” Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 174 (2000). As such, the plaintiffs have stated plausible claims, and must be permitted their “day in court” in order to have the substantive issues they raise decided on the merits after development of a full record.

PROCEDURAL HISTORY

The plaintiff filed a Verified Complaint and application for an Order to Show Cause on September 13, 2021, the day on which the Vaccine Passport took effect. Oral argument of the application for a preliminary injunction was heard October 8, 2021. The motion for a preliminary injunction was denied by Honorable Brian M. Cogan, U.S.D.J., on October 12, 2021. *Dixon v. DeBlasio*, 566 F. Supp. 3d 171 (E.D.N.Y. 2021).

Notice of Appeal was filed October 22, 2021. A motion for an expedited hearing was filed November 4, 2021. Opposition thereto was filed November 15, 2021. An Order granting the motion was entered November 19, 2021, and set the plaintiff’s briefing date at December 27, 2021, opposition on January 13, 2022, and a reply on February 14, 2022. A motion seeking further acceleration of the appeal was filed by the plaintiffs on November 24, 2021. The plaintiffs then filed their Brief and Appendices on November 29, 2021. Despite the plaintiffs having fully submitted early, defendants opposed the motion on December 6, 2021. The motion was denied on December 14, 2021. Defendants ultimately filed their responding brief on January 31, 2022, after seeking additional time to do so. On February 2, 2022, the plaintiffs moved to strike the responding brief for relying on voluminous evidence outside the record or alternatively seeking an extension of time to file a reply brief. Such motion was opposed by defendants on February 9, 2022, and the motion was denied in its entirety on February 11, 2022. The plaintiffs thus filed their reply brief on February 14, 2022.

Oral argument was scheduled for March 29, 2022. On March 7, 2022, Mayor Adams rescinded the Vaccine Passport. On March 9, 2022, defendants moved to dismiss the appeal as being moot. Opposition to such motion was filed on March 16, 2022, per Order of the Second Circuit. Said opposition noted that the issues were escaped review but were capable of repetition, and also noted that the Employer Mandate was based on the same alleged legal underpinnings, and specifically was in the news as related to its effect on New York baseball teams. On March 24, 2022, Mayor Adams rescinded the Employer Mandate, but only for sports teams, since it placed the teams at a competitive disadvantage. On March 26, 2022, the Second Circuit dismissed the appeal, remanded to the district court, and vacated the Order denying a preliminary injunction.

Also, on November 10, 2021, defendants requested a pre-motion conference with Judge Cogan which was converted by the Court to a Motion to dismiss, with a response being due December 8, 2021. Thereafter, several adjournments of such motion were obtained by the plaintiffs due to the pending appeal, and the changing of law firms by counsel for the plaintiffs. On April 6, 2022, request was made that the plaintiffs be permitted to file an Amended Complaint. A draft Amended Complaint was presented to the Court on May 4, 2022, via a letter motion, in keeping with the Court's Order regarding same. On May 25, 2022, opposition to the motion to dismiss was filed by the plaintiffs. On June 24, 2022, due to recent United States Supreme Court decisions, the plaintiffs requested leave to further revise the pending proposed Amended Complaint, and a formal motion to such effect was filed July 5, 2022. Opposition to such motion was filed August 5, 2022. This reply follows.

STATEMENT OF FACTS REPLY

The plaintiffs' proposed Amended Complaint includes the following additions from the Complaint:

- The action is to be brought on behalf of all similarly situated individuals and businesses;
- At least 25 EEO's are being challenged for illegality, since they all spring from the same lack of legal authority of Mayors de Blasio and Adams (*e.g.* ¶¶ 2, 35-44, 245, 249, 252)²;
- Recovery is sought for economic losses suffered by the named plaintiffs and related class members, as well as seeking vindication of their constitutional and statutory rights (*e.g.* ¶¶ 1, 66-71, 72, 76, 104-109, 112, 120, 188, 195, 200, 213, 234);
- Detailed additional allegations supporting the irrational nature of the EEOs, including that special exceptions have now been made for employees of sports teams only; even defendants' expert herein, Dr. Jay Varma, has been quoted as saying the special exemption is arbitrary and capricious and subjects the Employer Mandate to being voided by a legal challenge (*e.g.* ¶¶ 8-9, 30-33, 58, 195);
- Detailed allegations have been made regarding the unavailability of fully FDA approved vaccines, the gross ineffectiveness of the existing EUA vaccines based on the studies conducted by the "big three" pharmaceutical companies (Pfizer, Moderna, and Johnson & Johnson), and that the vaccines will never be able to create herd immunity, and will cause the Sars-CoV-2 ("Sars-2") virus to morph into variants which will increasingly cause harm to the vaccinated, not the unvaccinated, per the plaintiffs' expert submissions. (*e.g.* ¶¶ 77-87);
- The impact of the mandates on fundamental constitutional rights is more specifically alleged, including the relation of such allegations to recent decisions of the Supreme Court (*e.g.* ¶¶ 97-101, 201, 217, 234, 257);

² Paragraph notations refer to those in the proposed Amended Complaint.

- The prayer for relief has been modified to include more specific relief with respect to the preemption of the EEOs by the Statute, declaring the EEOs void for violating the Due Process, Equal Protection, and Privileges and Immunities clauses of the Constitution, and enjoining the Mayor from exercising the putative power to issue EEOs pursuant to what the plaintiffs contend is non-existent legal authority which otherwise is preempted and unconstitutional (*e.g.* Tenth Coung Prayer for Relief ¶¶A-F).

LEGAL ARGUMENT

POINT I: THE PROPOSED AMENDED COMPLAINT IS NOT MOOT.

In deciding defendants' motion, this Court is guided by the standard that "[a] party's motion to amend its complaint is governed by the liberal standard supplied by Federal Rule of Civil Procedure 15, which states that 'a court should freely give leave to amend when justice so requires.'" *Int'l Techs. Mktg. v. Verint Sys.*, 850 Fed. Appx. 38, 43 (2d Cir. 2021). (quoting *Holmes v. Grubman*, 568 F.3d 329, 334 (2d Cir. 2009) (internal alterations omitted) (quoting *Fed. R. Civ. P.* 15(a)(2)).

Defendants acknowledge that the plaintiffs seek to challenge all of the EEO's which have been promulgated, including the Employer Mandates which require businesses to require proof of vaccination from covered workers and maintain records of the same (Db 2). As with all prior EEOs, the Employer Mandate was promulgated without legal authority. The illegal and unconstitutional EEOs are pervasive across all aspects of City life, and have adversely affected the named plaintiffs and all those who are similarly situated as well, be they businesses or individuals. Injunctive, declaratory, and economic relief is sought against defendants. Economic damages are sought for the harm caused to the named plaintiffs and all similarly situated individuals and businesses for their forced compliance with unconstitutional and illegal EEOs (*e.g.* ¶112). An

injunction is sought preventing the ongoing EEO and future efforts by defendants to exercise such power--which power never has been acknowledged by defendants to be illegal, such that it is reserved unto them for the future. Finally, declaratory relief is sought which is specific to the alleged facts and the pertinent law.

Defendants correctly note that our federal courts may only decide live cases or controversies. (Db 3, citing *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 160 (2016)). Moreover, defendants correctly note that exceptions exist to the mootness doctrine including that “a defendant cannot automatically moot a case simply by ending its unlawful conduct once sued,” (Id., quoting *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013)), and when issues are “capable of repetition yet evading review.” (Id., quoting *Fed. Elec. Comm’n. v. Wisc. Rt. to Life*, 551 U.S. 449, 462 (2007); *Friends of Earth*, supra, 528 U.S. at 190). However, the remainder of defendants’ mootness arguments are fatally flawed.

Defendants, as admitted in their responding appellate brief, stake their entire argument as to mayoral authority on *N.Y. Exec. L.* § 24, which extends state-wide emergency powers to localities in “cases of ‘disaster, rioting, catastrophe or similar public emergency within the ... city ...’” Defendants claim that the pandemic was a “disaster.” However, all of the EEOs were promulgated after the State’s disaster declaration had been lifted by Mayor Cuomo. *N.Y. Exec. L.* § 28 specifically permits local governments to limit their emergency powers in the absence of a disaster declaration, and Code §§ 3-104 and 105 specifically limit the Mayor’s exercise of emergency powers to instances “of mass public unrest.” The Code does not give the Mayor the power to exercise emergency powers in any other situation, including in the case of pandemic, such that the EEOs were issued without legal authority. The Mayor has no legal ability to exercise power that have not been delegated to him through the peoples’ representatives.

Contrary to defendants' arguments, the issue of mayoral authority has not been decided in favor of the Mayor by any binding legal case such that the issue remains open (Db 11). The cases cited by defendants for the proposition that the issue is settled law do not analyze the fact that the State's disaster declaration had been terminated at the time the EEO's were promulgated, such that the Mayor was without authority to issue the EEOs under the Code. See Dixon, supra at 171, *vacated* 2022 U.S. App. LEXIS 8785 (2d Cir. March 28, 2022); *Bravo v. De Blasio*, 75 Misc. 3d 373, 384-85 (Sup. Ct. Kings Cty., 2022).³

Defendants admittedly are still enforcing the Employer Mandate. The EEOs which originally were the subject of this lawsuit, EEOs 225, 226, and 228 ("Vaccine Passport"), were only terminated in the days after the plaintiffs filed a reply brief with the Second Circuit setting forth arguments as to the Mayor's lack of legal authority to compel and enforce the Vaccine Passport mandate. While defendants may attempt to claim that the Vaccine Passport was terminated for reasons other than the plaintiffs' briefing, the plaintiffs allege the opposite, (¶¶ 29-34). The plaintiffs are entitled to have their allegations drawn in a light most favorable to them. *York v. Ass'n of the Bar*, 286 F.3d 122, 125 (2d Cir. 2002). Further, drawing favorable inferences for the plaintiffs, including that the Mayor vacated the Vaccine Passport so as to avoid review, the Amended Complaint is facially plausible in such regard. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.")

³ *Generoso v. Adams*, No. 528739/2021, 2022 NYLJ Lexis 116 at *7-10 (Sup. Ct. Kings Cnty. Feb. 10, 2022), could not be located in our LEXIS search and was termed to be "unavailable". Needless to say, as with all the cited cases, at worst *Generoso* is a non-precedential case of the state trial court.

Since the claims have evaded review and are capable of repetition, and since defendants have caused such evasion when the facts are drawn in a light most favorable to the plaintiffs, the claims are plausible, and should proceed to a review on the merits.

POINT II: THE PLAINTIFFS HAVE STANDING.

Defendants complain that only generalized allegations of injury are pled. (Db 6). However, with respect to standing, “[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss the Court “presum[es] that general allegations embrace those specific facts that are necessary to support the claim.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 889 (1990)).

The plaintiffs allege that they, and all similarly situated businesses and individuals, suffered economic harm and are entitled to an injunction and declaratory relief as well under §1983, due to official governmental policy. Such claims thus are appropriately being pursued pursuant to *Monell v. Dep't of Soc. Servs.*, 436 U.S. 658, 690-91(1978). Consequently, “[i]f a jury finds that a constitutional violation has been proven but that the plaintiff has not shown injury sufficient to warrant an award of compensatory damages, the plaintiff is entitled to an award of at least nominal damages as a matter of law.” *Robinson v. Cattaraugus Cty.*, 147 F.3d 153, 162 (2d Cir. 1998). No further inquiry need be made, since standing unquestionably exists.

POINT III: THE PLAINTIFFS STATE PLAUSIBLE CLAIMS.

Defendants seek dismissal based on “futility”. Thus, this Court “must analyze this claim under the traditional futility standard, i.e., whether it would withstand a motion to dismiss under *Fed.R.Civ.P.* 12(b)(6).” *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 114 (2d Cir. 2001). Such standard requires that the plaintiffs need “only enough facts to state a claim to relief that is

plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*, at 556. “The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Ibid.* “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of ‘entitlement to relief.’” *Ashcroft*, *supra*, 556 U.S. at 678 (quoting *Bell* at 557).

This Court’s preliminary ruling on many issues in *Dixon* provides a guidepost, but facts have changed as have allegations. **Indeed, Mayor Adams has exempted professional sports teams from the Employer Mandate while leaving it in place for all others. No better authority than defendant’s own expert who was been relied on to avoid a preliminary injunction sought in *Dixon*, Dr. Jay Varma, has written that the Employer Mandate “opens the City up to [the] entire scheme being voided by courts as ‘arbitrary and capricious’” (§33) (emphasis added).** Moreover, the standard of review here is different and much more forgiving than that which was considered for purposes of the plaintiffs seeking a preliminary injunction. Under such circumstances and the expanded nature of the suit which included a class of all individuals and businesses seeking to vindicate their rights (§1) close re-examination as to each cause of action is required in the interests of justice.

A. The Additional EEOs: The plaintiffs challenge all EEOs on grounds that like the Vaccine Passport, they all were illegally promulgated based on the same factors, as set forth above. The Mayor lacked authority to impose coercive vaccine measures based on a putative “emergency.” Likewise, as previously argued and further detailed, any such mandate is preempted by the Statute. Moreover, the Employer Mandate affects all business plaintiffs and individuals to the extent that

they were or wish to be employees within the City. The Employer Mandate is as equally illegal as the Vaccine Passport and suffers the identical legal flaws, as do all other EEOs. Thus, plausible claims are stated.

B. Equal Protection Based on Discrimination: In *Dixon*, 566 F. Supp. 3d at 180-81, this Court found that strict scrutiny was not required because the Vaccine Passport was facially neutral and was not applied discriminatorily. *Id.* at 180-81. However, such decision completely overlooked the allegations that African-Americans and Hispanics had been specifically targeted for months for voluntary vaccination, and such public policy effort failed. Thus, the Vaccine Passport was imposed, it is alleged, with the specific intent that it would cause harm to African-Americans if they did not begin to comply (§§ 190-195). The plaintiffs are entitled to discovery on such issues so as to be able to prove their allegation, which must be viewed most favorably to them. Thus, the claim is plausible.

C. Bodily Integrity/ Parental Rights/Right to Specific Employment: Defendants express curiosity over why the plaintiffs have relied *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2301 (2022) (Thomas, J., concurring), wherein Justice Thomas presented an orderly analysis of 14th Amendment jurisprudence which provided that enumerated constitutional rights are to receive strict scrutiny examination, and that non-enumerated fundamental rights are to be very carefully examined, if not strictly scrutinized. In *Meyer v. Nebraska*, 262 U.S. 390, 399-400 (1923), the Supreme Court held that the Constitution without doubt “denotes not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free

men.” The Court continued: “The established doctrine is that this liberty may not be interfered with, under the guise of protecting the public interest, by legislative action which is arbitrary or without reasonable relation to some purpose within the competency of the State to effect.” *Id.* at 400.

Jacobson v. Com. of Massachusetts, 197 U.S. 11, 30 (1905), holds no differently and specifically approved the exemptions in the subject **statute** for exceptions for children and unfit candidates for vaccination, such as plaintiffs Dixon, Rivera, Kabbez, and King. Here, the non-statutory EEOs do no such thing. In *Riggins v. Nevada*, 504 U.S. 127, 135-37 (1992), the Court applied what is akin to intermediate scrutiny in determining the propriety of compelling a prisoner to take antipsychotic medication, a standard which is more in line with Justice Thomas’ stated views about fundamental rights such as those related to bodily integrity, parental control of their childrens’ medical care, and the right to seek employment of one’s choosing. See also *Crawford v. Cushman*, 531 F.2d 1114, 1124-5 (2d Cir. 1976) (requiring a case-by-case individualized determinations as to bodily integrity). Particularly in light of an exemption being made for professional athletes, but not for those like the aforementioned plaintiffs that they should not receive the vaccine for health reasons, plausible claims have been stated such that the plaintiffs should be given the opportunity to undertake discovery to develop a full record on these issues so that a fully informed decision may be made at the appropriate time.

D. Religious Freedom: While most City residents likely are happy that the Mets and Yankees are having successful seasons, Mayor Adams’ exemption for professional athletes for reasons of their competitiveness, while not providing exemptions for religious objectors is, as Dr. Varma has stated, arbitrary and capricious, and plausibly violates the First Amendment of the Constitution.

E. **Privileges and Immunities:** The plaintiffs have briefed this argument previously, and expand it in light of Justice Thomas' *Dobbs* concurrence. The claims certainly require Supreme Court review since *Slaughterhouse Cases*, 83 U.S. 36 (1872). However, it is respectfully asserted that the facts herein present an excellent opportunity to do so since guardrails need to be established on state police powers as related to enumerated and fundamental rights which, the plaintiffs assert, may best be addressed in a construct similar to that discussed by Justice Thomas.

F. **Thirteenth Amendment:** The *Dixon* decision held that the Vaccine Passport requirements were no different that "ensuring bars do not serve patrons under the age of 21." Yet no law or even Executive Order even compels "carding." The Vaccine Passport required all types of businesses to check both identifications and vaccine cards at the door, without exception. Likewise, business owners now must check vaccination status of employees and maintain such records. Such mandates conscript individuals and businesses to become government agents under threat of coercive punishment, such that a plausible Thirteenth Amendment violation has been pled.

G. **Preemption:** Defendants avoid the very specific allegation of the proposed Amended Complaint to try turning the issue of preemption on its head. The Statute concerns EUA vaccines. Defendants argue that Pfizer and Moderna now have fully approved vaccines, such that the Statute does not apply. However, the Court must accept as true the plaintiffs' very specific allegations that such fully approved vaccines are not available to the general public, as documented by official FDA and pharmaceutical company documents in prior filings (¶¶ 61-62). Likewise, this Court must accept as true those allegations detailing that the EUA vaccines are neither safe nor effective (¶¶ 6, 77-87). Indeed, EUA vaccines unquestionably remain on the market, and may only be permitted when there are "no adequate, approved, and available alternative to the product." 21 U.S.C. § 360bbb-3(c)(3)-(4).

While it does not create a cause of action, “[t]o say that the *Supremacy Clause* does not confer a right of action is not to diminish the significant role that courts play in assuring the supremacy of federal law.” *Id.* at 478. It has long been recognized that “if an individual claims federal law immunizes him from state regulation, the court may issue an injunction upon finding the state regulatory actions preempted.” *Id.* (citing *Ex Parte Young*, 209 U.S. 123, 155-6 (1908)). Thus, “federal courts may in some circumstances grant injunctive relief against state officers who are violating, or planning to violate federal law.” *Id.* at 478. “[I]n a proper case, relief may be given in a court of equity ... to prevent an injurious act by a public officer.” *Id.* (quoting *Carroll v. Safford*, 44 U.S. 441 (1845)). Thus, the Declaratory Judgment Count of the proposed Amended Complaint serves as an important tool in seeking such relief.

Defendants next speciously assert that the Statute only applies to medical providers. (Db 14). The FDA is responsible for all things associated with the sale and use of drugs, vaccines, and therapeutics. The Statute provides every person with “*the option to accept or refuse administration of the product ...*” Only the greatest leap of logic can lead to the conclusion that the statutory informed consent dictate within the highly regulated FDA statutory structure would allow a city mayor essentially to put a choice to those faced with taking an EUA vaccine of either consenting, or losing their rights to society and other constitutional rights. **Indeed, the record contains an FDA position statement that state laws which provide additional or different requirements for EUA vaccines are preempted, and a separate detail of the FDA’s reasoning therefor also in the record.** (SA 114 and 107-109).⁴ “Considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations.” *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*,

⁴ Reference is to the Supplemental Appendix filed on appeal.

467 U.S. 837, 844 (1984). Thus, a preemption inference can be drawn with respect to regulation of conduct touched on by the Statute. *See Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (determining a private party's preemption challenge under 21 U.S.C. § 360k(a), which is one of the Statute's provisions).

The FDA's "informed consent" regulation leaves no room to doubt that coercion of any kind is prohibited, 45 C.F.R. § 45.116(b)(8), and further crystalizes the Statute's applicability to this matter (emphasis added): **"A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled."**

In other words, the refusal to be vaccinated may not be used as a basis to terminate employees or to refuse individuals' access to restaurants and gyms. Thus the plaintiffs state a plausible case that the EEOs are preempted.

CONCLUSION

For the foregoing reasons, leave should be given for the defendants' to file their Amended Complaint.

Respectfully yours,

MURRAY-NOLAN BERUTTI LLC

s/ *Ronald A. Berutti*

By: _____
Ronald A. Berutti

Dated: September 9, 2022